

REMARKS**Status of Claims**

Claims 1, 2, 4-30 and 55 were pending at the time of this Office Action (OA) and were rejected.

The Rejection Under 35 U.S.C. § 103**Shea in view of He**

Claims 1, 2, 4-15, 17-24, 30 and 55 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shea et al. (U.S. Patent Publication No.2003/0235825; hereinafter “Shea”) in view of He et al. (U.S. Patent No. 7,390,463; hereinafter “He”).

It is stated that Shea teaches device comprising a substrate (110) having a planer surface and a plurality of microarray areas (11/12) and wherein the substrate comprises an enclosure (3) attached to the substrate (Fig. 4, ¶ 90). It is stated that Shea teaches the device further comprising a cover having a supporting structure (i.e. snap-fit structure, Fig. 10A) projecting from the cover wherein the supporting structure defines the reaction space (¶ 58, 92-93). It is further stated that Shea teaches the device wherein each assay area (11/12) has an access port (7) for fluid delivery and removal (¶ 92). The Office acknowledges that Shea does not teach the port projecting into the reaction spaces. It is stated that fluidic access ports projecting into reaction spaces were known in the art at the time the invention was made as taught by He who teaches each reaction space having a projection for fluid delivery and removal wherein the projections “reduce the volume of reagents required to perform an assay, localize the use of reagent solution directly on the biological materials, and stimulate microfluidic flow” (paragraph spanning columns 7-8). The Office concludes that it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the projections of He to the fluidic access ports of Shea. Applicants respectfully traverse this rejection for the reasons set forth below.

The initial burden to make a *prima facie* case of obviousness is on the Examiner. *In re Bell*, 991 F.2d 781, 783 (Fed. Cir. 1993). To make a *prima facie* case of obviousness, the teachings of the prior art should have suggested the claimed subject matter to the person of ordinary skill in the art, and all the claim limitations must be taught or suggested in the references cited by the Examiner. *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000). Moreover, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. *See KSR Intl Co. v. Teleflex, Inc.*, 550 U.S. 398, 420 (2007).

The presently claimed invention relates to a microarray reaction device, which device comprises: a) a microarray chip comprising a planar surface and an enclosure attached to said microarray chip to form a microarray area on said planar surface; and b) a cover comprising a projection and a supporting structure that projects from said cover; wherein a reaction space is formed between said microarray area of said microarray chip and said projection of said cover, wherein the volume of said reaction space is controllable by the height of said supporting structure, the heights of said projection and the area of said projection, and wherein the thickness of said enclosure is less than the height of said supporting structure.

Shea fails to disclose the enclosure in the presently claimed invention, which not only functions as a sealing, but also forms the reaction space between the microarray area and the projection on the cover. Unlike the enclosure disclosed in the presently claimed invention, the assay area element (3) of Shea contains two sections (11/12), wherein each section has a recessed portion (9), which forms an assay area with the substrate (110). Shea further fails to disclose a cover comprising a projection. The snap-fit structure illustrated in Fig. 10A corresponds to the supporting structure of the presently claimed invention, but not the projection which forms a reaction space with the microarray area of the microarray chip. This becomes more obvious when the following passage is considered:

FIG. 6 shows the inner surface of assay area element 3, herein described with reference to section 11 for ease of description only. Section 11 of assay area element 3 has a recessed portion 9 such that when the base 1 and the cover 5 are snap-fit together, the assay area element 3 is positioned over the substrate 110, over an array 112, to provide an assay area, as mentioned above, defined by the enclosed area or

space between the substrate [110] and the recess 9. Accordingly, the assay area produced is substantially vapor and fluid tight due to the substantially vapor and fluid tight seal formed between the perimeter, i.e., the walls or edges of recess 9 and the substrate [110]. More specifically, when engaged, the snap-fit applies a pressure to the outer surface of the assay area element 3 directly above the recess 9 and more specifically to the perimeter of recess 9 to produce a substantially vapor and fluid tight seal with a substrate positioned on the base 1.

Shea at paragraph [0093] (emphasis added).

According to the above, the reaction areas are formed between the substrate (110) and the recessed portion (9), not between the microarray chip and the projection on the cover as claimed in the present invention. The snap-fit structure illustrated in Fig. 10A does not form a reaction area with the substrate (110) and thus does not equal the projection. Therefore, Shea fails to disclose a projection on the cover and a reaction area formed between the microarray chip and the projection.

He does not cure the deficiencies of Shea. He discloses a microfluidic device comprising a multi-well microplate and fluidic modules that can be inserted into an individual well of a microplate. *See* He at column 2, lines 34-53. However, He fails to teach an enclosure attached to the microarray chip to form a microarray area. On the other hand, the microarray areas are represented by the wells of the multi-well microplate.

Further, one of ordinary skill in the art would not have a reason or motivation to combine the teachings of Shea with those of He because doing so would have rendered the intended purpose of Shea unsatisfactory. *See* MPEP § 2142.01 ("If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.") (citations omitted). The support structure (10) disclosed by He cannot be used to substitute the assay area element (3) disclosed by Shea, as doing so would result in a structure unsuitable for the function of the Shea device: forming a plurality of reaction chambers for microarrays. The reaction chambers of Shea are formed between the flat substrate (110) and the recessed portion (9). However, the support structure (10) of He does not have any recessed portions, but rather microcolumns (32), which are not suitable to form reaction chambers with the flat substrate (110).

Therefore, combining the teachings of Shea with those of He does not teach or suggest the presently claimed invention. Further, modifying Shea with the teachings of He would have rendered the intended purpose of Shea unsatisfactory. Accordingly, the Examiner has failed to make a *prima facie* case of obviousness, and this rejection under 35 U.S.C. § 103(a) should properly be withdrawn.

Shea in view of He and further in view of Webb

Claims 16-18 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shea in view of He as applied to claim 1 and further in view of Webb et al. (U.S. Patent No. 7,332,328; hereinafter “Webb”). Applicants respectfully traverse this rejection for the reasons set forth below.

The legal standard for obviousness has been shown. As discussed above, combining the teachings of Shea with those of He does not teach or suggest the presently claimed invention. Further, modifying Shea with the teachings of He would have rendered the intended purpose of Shea unsatisfactory. Webb fails to cure the deficiencies of Shea and He. Webb discloses a device having a support structure with a planar surface, and a plurality of microcolumns which project away from the planar surface and fit into wells of a microtiter plate. *See* Webb at column 2, lines 31-67. Webb does not disclose the enclosure in the presently claimed invention, which not only functions as a sealing, but also forms the reaction space between the microarray areas and the projections on the cover.

Therefore, combining the teachings of Shea with those of He and Webb does not teach or suggest the presently claimed invention. Accordingly, the Examiner has failed to make a *prima facie* case of obviousness, and this rejection under 35 U.S.C. § 103(a) should properly be withdrawn.

Shea in view of He and further in view of MacBeath

Claims 25-29 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shea in view of He as applied to claim 1 and further in view of MacBeath et al. (U.S. Patent No. 7,063,979; hereinafter “MacBeath”). Applicants respectfully traverse this rejection for the reasons set forth below.

The legal standard for obviousness has been shown. As discussed above, combining the teachings of Shea with those of He does not teach or suggest the presently claimed invention. Further, modifying Shea with the teachings of He would have rendered the intended purpose of Shea unsatisfactory. MacBeath fails to cure the deficiencies of Shea and He because MacBeath does not disclose the projection as claimed in the present invention. MacBeath discloses a bottomless microtiter plate combined with substrates having microarrays through one or more perforated gaskets in such a way that the individual microarrays end up at the bottom of different wells of the plate, each separated from the other by a water-tight seal. MacBeath at column 1, line 54 – column 2, line 11. However, the bottomless microtiter plate of MacBeath does not include a projection on the cover and a reaction area formed between the microarray chip and the projection.

Therefore, combining the teachings of Shea with those of He and MacBeath does not teach or suggest the presently claimed invention. Accordingly, the Examiner has failed to make a *prima facie* case of obviousness, and this rejection under 35 U.S.C. § 103(a) should properly be withdrawn.

Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 514572002100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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